(h) Prior to starting any additional research involving human subjects, the contractor shall submit appropriate documentation to the Contracting Officer for institutional review and approval or exemption determination. This documentation may include:

(1) Copies of the human subjects research protocol, all questionnaires, surveys, advertisements, and informed consent forms approved by the cognizant IRB;

(2) Documentation of approval for the human subjects research protocol, questionnaires, surveys, advertisements, and informed consent forms by the cognizant IRB;

(3) Documentation of continuing IRB approval by the cognizant IRB at appropriate intervals as designated by the IRB, but not less than annually; and/or

(4) Documentation to support an exemption for the project from the Common Rule [*Note:* this option is not available for activities that fall under 45 CFR part 46 subpart C].

(i) In addition, if the contractor modifies a human subjects research protocol, questionnaire, survey, advertisement, or informed consent form approved by the cognizant IRB, the contractor shall submit a copy of all modified material along with documentation of approval for said modification by the cognizant IRB to the Contracting Officer for institutional review and approval. The contractor may not implement any IRB approved modification without written approval by the Contracting Officer.

No work involving human subjects may be undertaken, conducted, or costs incurred and/or charged to the project, until the Contracting Officer approves the required appropriate documentation in writing.

(End of clause)

[75 FR 10570, Mar. 8, 2010; 75 FR 14496, Mar. 26, 2010]

1352.235–72 Protection of human subjects—institutional approval.

As prescribed in 48 CFR 1335.006(c), insert the following clause:

PROTECTION OF HUMAN SUBJECTS—INSTITUTIONAL APPROVAL (APR 2010)

(a) This contract/order includes non-exempt human subjects research that must be conducted pursuant to the requirements of the Federal Policy for the Protection of Human Subjects (the ''Common Rule''), adopted by the Department of Commerce at 15 CFR part 27. Contractor has submitted documentation establishing review and approval of the human subjects research protocol, including all informed consent forms, advertisements, and other recruitment materials, by a qualified Institutional Review Board (IRB) that has a current Federal-wide Assurance (FWA) issued by the Department of Health and Human Services (DHHS).

(b) By accepting this contract/order, the contractor certifies the accuracy of the documentation provided to its cognizant IRB and to the Government in support of the human subjects research specified therein. Based upon the contractor's documentation, and following the Government institutional review thereof, the following specific involvement of human subjects in research is hereby approved by the Contracting Officer:

Name of IRB: _____

(IRB # _____)

Title of IRB Protocol: _____

Recruiting Letter Approval Date (if appropriate): _____

Consent Form Approval Date: _____

Assurance of Compliance Number: _____

(c) Unless incorporated by written contract modification approved by the Contracting Officer, no other involvement of human subjects in research under this contract may be undertaken or conducted, or costs incurred and/or charged to the project, except as specified in the study plan reviewed and approved by the cognizant IRB and Government. Therefore, if the contractor modifies a human subjects research protocol, advertisement, or informed consent form approved by the cognizant IRB, contractor shall submit a copy of all modified material, along with documentation of approval for said modification by the cognizant IRB, to the Contracting Officer for agency institutional review and approval. Contractor may not implement any IRB-approved modification without written approval by the Contracting Officer.

Documentation of continuing IRB approval is required each year by the renewal date assigned by the cognizant IRB. Documentation of continuing IRB approval must be submitted to the Government for review and approval as soon as it occurs. Continuing approval of the human subjects research must be obtained from the cognizant IRB and provided to the Government until the research is completed or terminated. The contractor may proceed with previously approved human subjects research, if any, under this contract while the Government is conducting continuing review and approval of the human subjects research protocol. In the event that the Government determines, during the course of its review, that the human subjects research in this contract is not in compliance with the regulations set forth at 15 CFR part 27, or this contract, the Contracting Officer may take the appropriate enforcement action, including disallowing costs, suspending or terminating the human subjects protocol or the contract, by notifying the contractor in writing.

(d) It is incumbent upon contractor to ensure that continuing IRB review approval occurs in accordance with 15 CFR part 27. In the event that continuing review approval does not occur as set forth by 15 CFR part 27, contractor is to notify the Contracting Officer immediately.

(e) Contractor must report all adverse events to the cognizant IRB and to the Contracting Officer. In the event that adverse events are reported to the cognizant IRB and the Contracting Officer, the Government may suspend this contract pending a full review of the adverse event by the cognizant IRB.

(f) If the conditions upon which IRB approval is based should change in any way, contractor shall immediately notify the Contracting Officer, in writing, of the specified change.

(g) Failure to comply with this contract clause will be considered material noncompliance with the contract, and the Contracting Officer may take appropriate enforcement action, including disallowing costs, suspension or termination of the contract.

(End of clause)

[75 FR 10570, Mar. 8, 2010; 75 FR 14496, Mar. 26, 2010]

1352.235–73 Research involving human subjects—after initial contract award.

As prescribed in 48 CFR 1335.006(d), insert the following clause:

RESEARCH INVOLVING HUMAN SUBJECTS—AFTER INITIAL CONTRACT AWARD (APR 2010)

(a) No research involving human subjects is currently included in this contract/task order, and no research involving human subjects is permitted under this contract/task order unless expressly authorized, in writing, by the Contracting Officer.

(b) The Federal Policy for the Protection of Human Subjects (the ''Common Rule''), adopted by the Department of Commerce at 15 CFR part 27, requires that contractors maintain appropriate policies and procedures for the protection of human subjects in research. The Common Rule defines a ''human subject'' as a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The term ''research'' means a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

(c) The Common Rule also sets forth categories of research that may be considered exempt from this policy. These categories are specified at 15 CFR 27.101(b).

(d) In the event that human subjects research involves pregnant women, prisoners, or children, the contractor is also required to follow the guidelines set forth at 45 CFR part 46 subparts B, C and D, as appropriate, for the protection of members of a protected class.

(e) Should research involving human subjects become necessary for carrying out this contract/task order, prior to undertaking or conducting such human subjects research, contractor shall submit the following documentation to the Contracting Officer:

(1) Documentation to verify that contractor has established a relationship with an appropriate Institutional Review Board (''cognizant IRB''). An appropriate IRB is one that is located within the United States and within the community in which the human subjects research will be conducted;

(2) Documentation to verify that the cognizant IRB is registered with the United States Department of Health and Human Services' Office for Human Research Protections (''OHRP'');

(3) Documentation to verify that contractor has a valid Federal-wide Assurance (FWA) issued by the OHRP.

(f) Prior to starting any research involving human subjects, contractor shall submit appropriate documentation to the Contracting Officer for Government institutional review and approval. This documentation may include:

(1) Copies of the human subjects research protocol, advertisements, recruitment material, and informed consent forms approved by the cognizant IRB;

(2) Documentation of approval for the human subjects research protocol, advertisements, recruitment material, and informed consent forms by the cognizant IRB;

(3) Documentation of continuing IRB approval by the cognizant IRB at appropriate intervals as designated by the IRB, but not less than annually; and/or

(4) Documentation to support an exemption for the project from the Common Rule [*Note:* this option is not available for activities that fall under 45 CFR part 46 subpart C].

(g) In addition, if contractor modifies a human subjects research protocol, advertisement, recruitment material, or informed consent form approved by the cognizant IRB, contractor shall submit a copy of all modified material, along with documentation of approval for said modification by the cognizant IRB, to the Contracting Officer for Agency institutional review and approval. Contractor may not implement any IRB-approved modification without written approval by the Contracting Officer.

(h) No work involving human subjects may be undertaken, conducted, or costs incurred